

**REMARKS**

Claims 1-13 and 15-21 are pending in the Application. Applicant notes with appreciation the allowance of claims 1-7 and the conditional allowance of claim 9. Applicant also wishes to thank the Examiner for kindly taking the time to discuss the Application.

Claim 9 has been rewritten in independent form. Claims 8, 13, 16 and 18 have been amended.

**Rejections under 35 U.S.C. § 102**

**Independent claims 8, 11, 13 and 16**

Claims 8 and 11 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,545,229 to Parsons et al. ("Parsons"). Claim 13 stands rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,019,792 to Cauthen ("Cauthen"). Claim 16 stands rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,888,226 to Rogozinski ("Rogozinski"). As the PTO provides in MPEP § 2131, "[t]o anticipate a claim, the reference must teach every element of the claim...." Therefore, the respective patents must disclose all of the elements of the respective claims to sustain the rejections. Accordingly, Applicant respectfully traverses those rejections on the following grounds.

**Independent claims 8 and 11**

Claim 8, as amended, recites in part: "the prosthesis comprising an upper half housing of a cylindrical housing engaging the cephalad vertebral bone inferior end plate ...." (emphasis added).

Parsons fails to teach or suggest each element of claim 8 as required by MPEP § 2131. More specifically, Parsons fails to teach or suggest a cylindrical housing. (emphasis added). For example, Parsons recites the following:

The functional and biocompatible intervertebral spacer of the present invention comprises a central core 2 of a soft biocompatible elastomer shaped and sized so as to approximate the shape and size of a nucleus pulposus of a natural intervertebral disc; an outer ring 4 of

stiffer elastomeric material surrounding said central core to approximate the size and shape of a natural annulus fibrosus; and endplates 8 and 10 comprised of a suitably stiff biocompatible material and affixed, one to each end, to the outer ring/central core. In a preferred embodiment, the core 2 will consist of 20-50% of the area of the spacer, and the outer ring 4 will consist of 50-80% of the area of the spacer. The relative size of the central core and the thickness of the outer ring in the radial direction, as well as the selection of material hardness, can be varied in order to more finely match the mechanical properties of the composite prosthesis to that of the normal disc. (col. 4, lines 7-23) (emphasis added)

Therefore, Parsons fails to disclose or suggest a cylindrical housing as recited by claim 8. Accordingly, Parsons fails to teach or suggest each element of claim 8 as required by MPEP § 2131, and claim 8 is allowable over the cited reference.

Claim 11 includes elements similar to those described above with respect to claim 8 and therefore, is also allowable over Parsons for at least the same reasons stated above with respect to claim 8.

#### Independent claim 13

Claim 13, as amended, recites in part: “A plurality of disc prostheses located within a human spine, each prosthesis comprising an upper half housing engaging a bearing surface of a cephalad bone inferior end plate ....” (emphasis added).

Cauthen fails to teach or suggest each element of claim 13 as required by MPEP § 2131. More specifically, Cauthen fails to teach or suggest an upper half housing engaging a bearing surface of a cephalad bone inferior end plate. (emphasis added). For example, Cauthen recites the following:

The invention relates generally to a spinal implant for use in intervertebral disc replacement; and more specifically relates to an articulating implant that fuses to adjacent

vertebrae by bone ingrowth, thus restoring proper intervertebral spacing, and eliminating nerve root and/or spinal cord compression, while preserving spinal flexibility. (col. 1, lines 5-10) (emphasis added)

Therefore, contrary to claim 13, which discloses an upper half housing engaging a bearing surface of a cephalad bone inferior end plate, Cauthen recites an articulating implant that fuses to adjacent vertebrae. Accordingly, Cauthen fails to teach or suggest each element of claim 13 as required by MPEP § 2131, and claim 13 is allowable over the cited reference.

#### Independent claim 16

Claim 16, as amended, recites in part: “wherein a cylindrical housing comprises the upper and corner half housings” (emphasis added).

Rogozinski fails to teach or suggest each element of claim 16 as required by MPEP § 2131. More specifically, Rogozinski fails to teach or suggest a cylindrical housing. (emphasis added). For example, Rogozinski recites the following:

A self-centering prosthetic disc to replace a disc in the spine, the disc having two opposing convex surfaces where the point of maximum vertical dimension is non-central. The disc may be utilized alone or in combination with one or two vertebral attachment members, the vertebral attachment members having concave surfaces corresponding to the convex surfaces of the disc. (abstract) (emphasis added)

Therefore, contrary to claim 16, which discloses a cylindrical housing, Rogozinski recites opposing convex surfaces where the point of maximum vertical dimension is non-central.

Therefore, Rogozinski fails to disclose or suggest a cylindrical housing as recited by claim 16. Accordingly, Rogozinski fails to teach or suggest each element of claim 16 as required by MPEP § 2131, and claim 16 is allowable over the cited reference.

**Rejections under 35 U.S.C. § 103**

**Independent claim 18**

\*Claim 18 stands rejected under 35 U.S.C. § 103 as being unpatentable over Rogozinski in view of Cauthen.

Pursuant to MPEP § 2142, “[i]f the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness.” It is submitted that the Office action fails to factually support a prima facie case of obviousness based on Rogozinski and Cauthen for the following reasons.

**A. Even When Combined, the References Do Not Teach the Claimed Subject Matter**

MPEP § 2143 requires that “[t]o establish a prima facie case of obviousness, ... the prior art reference (or references when combined) must teach or suggest all the claim limitations.”

Claim 18, as amended, recites in part: "A disc prosthesis comprising: a cylindrical housing, comprising at least two rigid, confronting and complimentary parts, each having an exterior surface together defining a general continuous thread formation, and each having an interior surface at least a portion of which is concave ...." (emphasis added)

However, the cited text of Rogozinski and Cauthen fails to teach or suggest the highlighted elements. For example, Rogozinski recites:

A self-centering prosthetic disc to replace a disc in the spine, the disc having two opposing convex surfaces where the point of maximum vertical dimension is non-central. The disc may be utilized alone or in combination with one or two vertebral attachment members, the vertebral attachment members having concave surfaces corresponding to the convex surfaces of the disc. (abstract) (emphasis added)

Therefore, contrary to claim 18, which discloses a cylindrical housing, Rogozinski recites opposing convex surfaces where the point of maximum vertical dimension is non-central.

Accordingly, the combination of Rogozinski and Cauthen fails to teach or suggest all the claim limitations of claim 18 as required by MPEP § 2143. As a result, claim 18 should be

allowed.

**B. The Combination of References is Improper**

Assuming, arguendo, that none of the above arguments for non-obviousness applies (which is clearly not correct, for reasons described previously), there is still another independent reason why the above-cited references cannot be applied to reject claim 18 under 35 U.S.C. §103.

§ 2142 of the MPEP provides:

*[T]he examiner must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made. . . . the examiner must then make a determination whether the claimed invention 'as a whole' would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination . . . .*

Here, neither of the cited references teaches, or even suggests, the desirability of the combination since neither of them teaches the specific arrangement as claimed in claim 18. Thus, it is clear that neither of the cited references provides any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103 rejection.

In this context, the MPEP further provides in §2143.01: The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. (emphasis added). Also, the courts have repeatedly held that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination.

In the present case, it is clear that the combination arises solely from hindsight based on Applicant's disclosure without any showing, suggestion, incentive or motivation in any of the references for the combination as applied to claim 18. Therefore, for this reason alone, the Examiner's burden of factually supporting a prima facie case of obviousness has clearly not been met, and the rejection of claim 18 under 35 U.S.C. § 103 should be withdrawn.

Accordingly, claim 18 should be allowed.

Dependent claims

Dependent claims 9-10, 12, 15, 17 and 19-21 depend from and further limit claims 8, 11, 13, 16 and 18, and should also be allowed.

Conclusion

As a result of the foregoing, it is respectfully asserted that all of the claims of the Application are in condition for allowance. Should the Examiner deem that any further amendment is desirable to place this application in condition for allowance, the Examiner is invited to telephone the undersigned at the below listed telephone number.

The Examiner is invited to contact the undersigned at the numbers provided below if further consideration is required. Also, Deposit Account No. 08-1394 may be used for any over or under payments.

Respectfully submitted,



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